September 4, 2018

Amsino International, Inc.
Cathy Hong
Senior RA Specialist
708 Corporate Center Drive
Pomona, CA 91768

Re: K181814
Trade/Device Name: AMSure® Pre-filled Syringe for Balloon Inflation with Sterile Water
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZL
Dated: July 6, 2018
Received: July 9, 2018

Dear Cathy Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Glenn B. Bell -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K181814

Device Name
AMSure® Pre-filled Syringe for Balloon Inflation with Sterile Water

Indications for Use *(Describe)*
Pre-filled Syringe for Balloon Inflation with Sterile Water is intended to be used in inflating foley catheter balloon.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## Section 5: 510(k) Summary

- **Submitter Information**

Submitter: Amsino International Inc.
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Contact Person: Cathy Hong
Senior RA Specialist
Phone: +86(21)-69117118
Fax: +86(21)-59148142
E-mail: Cathy_Hong@amsino.com
Date Prepared: July 06, 2018

- **Device Information**

Common or Usual Name: Pre-filled Syringe for Balloon Inflation with Sterile Water

Trade or Proprietary Name: AMSure® Pre-filled Syringe for Balloon Inflation with Sterile Water

Product Item: CIS1003, CIS1005, CIS1010, CIS3530

Regulation Number: 876.5130
Classification Name: Urological Catheter and Accessories
Device Class: Class II
Review Panel: Gastroenterology/Urology
Product Code: EZL

- **Predicate Device Information**

Device Name: Primary Care Solution Pre-Filled 10cc and Pre-Filled 30cc Inflation Syringe with Sterile Water

510(k) Number: K030813

- **Device Description:**

- The AMSure® Pre-filled Syringe for Balloon Inflation with Sterile Water is a 3cc, 5cc, 10cc and 30cc syringe pre-filled with USP purified water and gamma irradiated. The syringe is produced using polypropylene for the device barrel and plunger and

pharmaceutical grade latex free rubber for both the plunger gasket and syringe tip cover. The shelf life of AMSure® Pre-filled Syringe for Balloon Inflation with Sterile Water is 3 years.

There is no prior submission for the AMSure® Pre-filled Syringe for Balloon Inflation with Sterile Water.

- **Indications for Use**

  Pre-filled Syringe for Balloon Inflation with Sterile Water is intended to be used in inflating foley catheter balloon.

- **Product Comparison Summary**

  The proposed AMSure® Pre-filled Syringe for Balloon Inflation with Sterile Water is equivalent to the Primary Care Solution, Inc.'s Primary Care Solution Pre-Filled 10cc and Pre-Filled 30cc Inflation Syringe with Sterile Water. The proposed device has the same indications for use, same operation principle, and the same general characteristics with the predicate device.

  The design and materials of the proposed devices are identical to the predicate device (K030813).

| No. | Device Characteristic | Predicate Device | Proposed Device | Comparison Results |
|---|---|---|---|---|
| 1 | **Product Code** | EZL | EZL | Same |
| 2 | **Indications for Use** | A sterile water pre-filled syringe for use in inflating foley catheter balloon. | A sterile water pre-filled syringe for use in inflating foley catheter balloon. | Same |

| | | | | |
|---|---|---|---|---|
| 3 | **Regulation Number** | 876.5130 | 876.5130 | Same |
| 4 | **Design Configuration** |  |  | Similar |
| 5 | **Principle of Operation** | Normal | Normal | Same |
| 6 | **Materials of main components** | | | |
| | Barrel | Polypropylene | Polypropylene | Same |
| | Plunger | Polypropylene | Polypropylene | |
| | Plunger Gasket | Black pharmaceutical grade, synthetic rubber (Latex free) | Black pharmaceutical grade, synthetic rubber (Latex free) | |
| | Tip Cover | Same as gasket | Same as gasket | |
| | Solution | Purified water, USP | Purified water, USP | |
| 7 | **Technical Performance** | Conform with ISO7886-1, ISO 80369-7 and USP 31 | Conform with ISO7886-1, ISO 80369-7 and USP 40. | Similar |
| 8 | **Biological evaluation** | Conform with ISO 10993-5, ISO 10993-10 requirements | Conform with ISO 10993-5, ISO 10993-10 requirements | Same |
| **9** | **Sterile method** | Gamma Irradiation | Gamma Irradiation | Same |

| | | | | |
|---|---|---|---|---|
| 10 | **Single Use/Reusable** | Single Use | Single Use | Same |

The AMSure® Pre-filled Syringe for Balloon Inflation with Sterile Water has the same indications for use and function as the predicate device. The syringe used for the predicate device and proposed device is the same made by Amsino Medical (Kunshan) Co., Ltd. The standards used for the performance test of the proposed device are the latest ones, and the test results meet its requirements.

- **Performance Data**

  The AMSure® Pre-filled Syringe for Balloon Inflation with Sterile Water meet the acceptance criterion for all functional, sterility, biocompatibility and other performance criteria which verify it to be substantially equivalent to the predicate devices. Results of the testing demonstrate that there are no new issues of safety and efficacy that are raised with the AMSure® Pre-filled Syringe for Balloon Inflation with Sterile Water.

- **Conclusions**

  The information provided within this pre-market notification demonstrates that the AMSure® Pre-filled Syringe for Balloon Inflation with Sterile Water is substantially equivalent to the predicate device.

***End of Summary***